UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Bristol-Myers Squibb Company CVR Securities Litigation	No. 1:21-CV-08255-JMF ORAL ARGUMENT REQUESTED

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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PRELIMINARY STATEMENT

To acquire Celgene, Defendant Bristol Myers Squibb Company ("Bristol") agreed to pay Celgene shareholders ***$6.4 billion*** if, and only if, three key Celgene drugs received FDA approval by certain "milestone" dates—December 31, 2020 for two of the drugs, and March 31, 2021 for the third drug. Under this very unusual deal structure, insisted upon by Bristol, if ***one*** of those three drugs missed its milestone date by even a ***single day***, those Celgene shareholders would get ***nothing***. Bristol orchestrated that very outcome, ensuring that Liso-cel, one of the three drugs, missed its December 31, 2020 milestone date by 36 days—saving Bristol $6.4 billion while also allowing it to financially benefit from Liso-cel's approval nearly right away—by ***deliberately delaying*** the portions of the FDA approval process they controlled.

The FDA did everything it could to approve Liso-cel quickly, giving it special designations that entitled it to a fast-tracked approval process. But when Bristol took over Celgene, the FDA approval process for Liso-cel suddenly took a peculiar turn and suffered a remarkable string of avoidable errors, each one of which would have been highly unusual for Bristol, and each one of which delayed but did not derail FDA approval—thereby maximizing Bristol's financial outlook.

For example, Bristol inexplicably took 29 days after taking over Celgene to submit the Chemistry, Manufacturing and Controls ("CMC") module of Liso-cel's Biologics License Application ("BLA"), and despite the additional time failed to include basic data with its FDA submission—which Bristol indisputably had and knew was required by the FDA—and instead only submitted summaries of that data. After receiving the FDA's inevitable request for the missing data, Bristol delayed providing it for over three weeks, and what it eventually submitted led to a further 90-day delay of the target approval date. Bristol also failed to fix easily solvable problems of which it was aware at the two Liso-cel manufacturing facilities ahead of the FDA's planned inspections. After the FDA identified deficiencies at the first facility, Bristol took the

maximum time allowed, and twice as long as usual, to respond. After the FDA identified further deficiencies both with the response and the second facility, Bristol took until December 23, 2020—***just days*** before Liso-cel's December 31, 2020 milestone date—to complete its responses. According to the FDA Biologics Expert[1]—who has worked as a senior reviewer and inspector in the FDA division responsible for drugs like Liso-cel—these errors and delays were highly unusual.

Defendants claim that each and every one of these unusual events and the delays they caused were coincidences, unrelated to each other or to the fact that they saved Bristol $6.4 billion. This counter-narrative is not credible. The facts alleged here (to be taken as true) compel the conclusion that the delays were calculated—not coincidental. Liso-cel is the ***only*** drug manufactured by Bristol or Celgene in the last eight years, and the ***only*** comparable therapy manufactured by ***any*** drug company, to have experienced this many easily avoidable delays in the FDA approval process. Bristol obtained FDA approval for Liso-cel ***415 days*** after its initial BLA filing, more than ***twice*** the 194-day average time for FDA approval of similar therapies and ***nearly double*** the average time for FDA approval for the other nine therapies Bristol and Celgene submitted for approval between July 2014 and 2020 (221.6 days). It is much more plausible that this series of highly abnormal failures by Bristol—all of which had the same effect of delaying, but not derailing, FDA approval—were designed to accomplish just that and help Bristol avoid a $6.4 billion payout while profiting from Liso-cel as shortly as possible thereafter.

[1] The FDA Biologics Expert previously served as a senior reviewer and lead inspector in the Division of Manufacturing and Product Quality at the Center for Biologics Evaluation and Research, Food and Drug Administration, which is the Division responsible for drugs like Liso-cel. While at the FDA, the FDA Biologics Expert led inspections of manufacturing facilities, including numerous pre-licensing inspections for facilities producing biologic drugs. The FDA Biologics Expert also reviewed regulatory submissions for such products, including leading reviews of the CMC sections of BLAs. The FDA Biologics Expert's current job as a consultant for pharmaceutical companies includes leading mock audits of manufacturing facilities preparing for pre-licensing inspections by the FDA, including for biologics like Liso-cel. ¶ 4 n.1.

Defendants also claim the COVID-19 pandemic caused their delays. This is demonstrably false, as numerous biologics were approved during the pandemic faster than Liso-cel—like rival drug Tecartus, submitted for approval at nearly the same time as Liso-cel, but approved ***six months*** faster. Had Liso-cel proceeded like Tecartus, it would have hit its milestone 153 days early.

Starting with the February 22, 2019 Registration Statement and Joint Proxy ("Joint Proxy") and continuing through November 16, 2020, Defendants falsely told investors that Bristol was using "diligent efforts" to achieve FDA approval before the milestones, that it was highly motivated to pay out the CVRs, and that any failure to secure Liso-cel's approval by the milestone date was caused by COVID-19—all while they secretly slow-rolled the Liso-cel approval process so Bristol could avoid the $6.4 billion CVR payout. Thus, Defendants' motion should be denied.

FACTUAL ALLEGATIONS

Bristol is one of the world's largest pharmaceutical companies. ¶ 44.[2] For years, Defendants Giovanni Caforio (Chief Executive Officer), David Elkins (Chief Financial Officer), and Samit Hirawat (Chief Medical Officer) have been its most senior executives. ¶¶ 46-48.

In 2018, Bristol offered to buy Celgene, mainly to acquire its pipeline of five drugs slated for imminent U.S. Food and Drug Administration ("FDA") approval. ¶¶ 9-10, 65. Bristol and Celgene ultimately agreed on a deal whereby Celgene's shareholders would receive Contingent Value Rights ("CVRs")[3] as partial consideration for the merger. ¶¶ 13, 80. Per standard industry practice, Celgene proposed structuring the CVRs, via a "CVR Agreement," to provide a separate $2 per share payout to CVR holders upon FDA approval of each of the five Celgene pipeline drugs,

[2] "¶ __" refers to the Consolidated Amended Class Action Complaint (ECF No. 95). "DB __" refers to Defendants' memorandum of law in support of their motion to dismiss (ECF No. 100).

[3] A CVR is a security payable upon the occurrence of a specific future event. ¶ 1.

for a total potential payout of $10 per share.[4] But Bristol insisted on an atypical "all-or-nothing" approach under which Bristol would pay $9 per share[5] only if ***all three*** of the pipeline drugs were approved prior to specific milestone dates: (1) Liso-cel by December 31, 2020, (2) Ozanimod by December 31, 2020, and (3) Ide-cel by March 31, 2021 ("Milestone Drugs"). ¶¶ 14-15, 80-81.

Bristol represented it would use "diligent efforts" to ensure the Milestone Drugs' approval by the milestone dates, including "such effort and employ[] such resources normally used [for] . . . development or commercialization of" these drugs, benchmarked against other drugs with "similar market potential at a similar stage in its development or product life." ¶ 16.

Liso-cel, one of the Milestone Drugs, is a cancer therapy for Non-Hodgkin's lymphoma, a cancer that kills approximately 20,000 Americans and 250,000 people worldwide each year. ¶¶ 1-2, 11. Liso-cel was so important to treating this disease that the FDA designated it a "Breakthrough Therapy," "Regenerative Medicine Advanced Therapy," and a "Priority Review" therapy, entitling it to an expedited approval process conducted by a dedicated team of senior FDA personnel devoted to ensuring it would enter the market as soon as possible. ¶¶ 2, 11, 82-83.

Liso-cel is a "biologic" drug. To sell a biologic in the United States, a company must submit a BLA to the FDA. The most important module of a BLA is the CMC module, which includes a detailed description of the manufacturing process and analyses of its safety. ¶¶ 20, 96.

Before the merger, Celgene was on track to secure FDA approvals of all three Milestone Drugs ***well before*** their milestone dates. ¶¶ 12, 72-78, 82, 95. Celgene submitted the first component of the Liso-cel BLA on September 30, 2019, before the merger closed, without issue.

[4] As consideration for the merger, the existing Celgene shareholders received one CVR with a potential payout valued at $9, along with one share of Bristol common stock and $50 in cash, for each share of Celgene common stock they owned. ¶ 17.

[5] Throughout the Class Period, more than 715 million CVRs traded on the NYSE. ¶ 236.

After the merger closed on November 20, 2019, Bristol took control of Liso-cel's FDA approval process. ¶¶ 18, 95-96. At this time, FDA's target approval date[6] for Liso-cel was August 17, 2020—***four and a half months*** before the Liso-cel milestone date. ¶ 98.

It was here that the Liso-cel approval process suddenly took a peculiar turn. First, there was an unusual and unexplained pause of about a month in the BLA submissions for Liso-cel between Bristol taking over the FDA application process and Bristol submitting the CMC module on December 18, 2019. ¶¶ 18, 96. According to the FDA Biologics Expert, submitting key parts of the BLA's CMC section 79 days (September 30, 2019 to December 18, 2019) after the rest of the application was an "unusually long period of time." ¶ 96. Despite this delay, Bristol omitted basic data detailing tests of Liso-cel's safety and efficacy (*i.e.*, assays) and studies assessing whether those tests were accurate (*i.e.*, validation)—***data required by the FDA and which Bristol does not dispute it had in its possession***—and instead included facially inadequate "summaries" of the required assays and validation. ¶¶ 4, 20-22, 99. According to the FDA Biologics Expert, a company "seeking approval of a biologic would ***not*** have omitted such assays from its BLA" and would understand "that omitting such assays could significantly delay FDA approval." ¶ 99.

The FDA completed its initial review of the Liso-cel BLA on February 13, 2020, and on March 23, 2020, FDA asked Bristol to submit the missing data. Bizarrely, Bristol did not respond ***for over three weeks***—even though the data was at Bristol's fingertips.[7] The FDA Biologics Expert called this delay "highly unusual." ¶ 100. When Bristol ***finally*** amended the Liso-cel BLA on April

[6] The target date is the FDA's Prescription Drug User Fee Act ("PDUFA") target approval deadline (which is why it is also called the "PDUFA date"). ¶ 24.

[7] Defendants ignore the fact that the FDA requested the missing data on March 23, 2020. Bristol waited until April 15, 2020 to respond—an unnecessary delay of 23 days. *See* DB 7; ¶ 100.

15, 2020, the FDA took the rare step of issuing a "Major Amendment"[8] because Bristol failed to include information it could have and should have included in its original CMC submission. *See* ¶ 100. This automatically extended the FDA's target approval date by ***90 days***, from August 17, 2020 to November 16, 2020 (just 45 days before the Liso-cel milestone date) and caused the rescheduling of the inspection of the two Liso-cel manufacturing facilities from June 2020 to October and December 2020 (mere weeks before the deadline). ¶¶ 23-25, 102.

Bristol then ***deliberately*** caused further delays in the facility inspections. ¶¶ 103, 107, 116. Multiple former employees confirmed Bristol ***knew*** Liso-cel's manufacturing facilities were unprepared for FDA inspections due to a litany of basic deficiencies of the sort that any large pharmaceutical company like Bristol could have easily remediated. ¶¶ 4-5, 27, 105, 118-26. Despite additional weeks to prepare, Bristol failed to address these numerous easily solvable issues—an assessment echoed by Plaintiffs' FDA Biologics Expert. *Id*. For example, the Lonza Facility lacked separate storage areas for materials to avoid mix-ups; labeled its materials in a manner that made mix-ups likely, or failed to label materials at all; had poorly maintained and poorly organized freezer bins; had a deficient inventory management system; failed to lock freezers containing quarantined material; and failed to timely ensure expired materials were properly discarded. ¶ 121. Multiple confidential witnesses ("CWs") stated these issues were known well in advance of the inspections, and the FDA Biologics Expert confirmed these issues should have been identified during routine mock inspections or other preparations and could easily have

[8] The criteria for whether the FDA will deem a supplemental submission to be a Major Amendment are laid out in the FDA's Standard Operating Policies & Procedures ("SOPP") 8402, which are publicly available on the FDA's website and would have been known to Bristol. *See* FDA, *SOPP 8402* (Dec. 11, 2020), *available at* https://www.fda.gov/media/84431/download. Bristol must have known or was reckless in not knowing its supplemental submission would be deemed a Major Amendment because it constituted a "substantial amount of new manufacturing or facility information not previously submitted to or reviewed by the Agency." *Id.* § V.E.2.

been fixed prior to the FDA inspections—yet Bristol failed to do so. ¶¶ 120-25.

Further, instead of sending experienced personnel to oversee the FDA inspection process, Bristol chose to send a junior employee with no experience working on an FDA pre-approval inspection, a highly unusual move contrary to standard industry practice. ¶ 115. Bristol did not disclose any of these issues to investors or fix them prior to the FDA inspections. Instead, it falsely told investors Liso-cel's manufacturing facilities were "launch ready." ¶ 106.

Following the conclusion of the inspections on October 16 and December 10, 2020, the FDA issued Forms 483 (*i.e.*, reports detailing violations of FDA regulations) for ***both*** facilities, requiring a response and remediation plan. ¶¶ 28, 107-12, 116-26. According to the FDA Biologics Expert, these violations were unusual and easily avoidable errors that any company that licenses biological products should not have committed. ¶¶ 107-126. Bristol took ***21 calendar days*** to respond to the first Form 483—even though according to the FDA Biologics Expert, it could easily have done so in 10 calendar days. ¶ 113. Bristol then submitted its response to the second Form 483 on December 23, 2020—***just days*** before Liso-cel's December 31, 2020 milestone. ¶ 126. Bristol's responses to both Forms 483 were also deficient, causing further delay. ¶¶ 113-14, 126.

In addition, Bristol simultaneously slow-rolled the FDA approval of Ide-cel, the third Milestone Drug, as a backup plan to maximize its odds of avoiding the $6.4 billion CVR payout. ¶ 132. Bristol deliberately submitted deficient filings for Ide-cel and received a "Refuse to File" letter from the FDA, an exceedingly rare response reserved for submissions with omissions of clearly necessary information or inadequacies so severe as to render the application incomplete on its face. ¶¶ 132-34. As a securities analyst noted, this deficiency was extremely unusual because Bristol "knows how to complete a regulatory application . . . and for [Ide-cel] it seems to have had no issue in Europe." ¶ 134. Bristol thus put itself within striking distance of missing the Ide-cel

milestone of March 31, 2021—just one more delay would do the trick. ¶ 135.

After the delays caused by Bristol's series of highly unusual "errors," which prevented approval of Liso-cel by the December 31, 2020 milestone date, the FDA finally approved Liso-cel's BLA on February 5, 2021—36 days after the milestone date lapsed, destroying $6.4 billion in shareholder value for the CVR holders. ¶¶ 6, 33, 127, 182. After missing the Liso-cel milestone, when delay of the Ide-cel approval was no longer in Bristol's financial interest, Bristol seemingly miraculously recovered its competence and secured FDA approval without any further issue for Ide-cel on March 26, 2021, five days before its milestone date.[9] ¶¶ 135, 216.

For a Breakthrough Designation drug like Liso-cel to take as long as it did to be approved is essentially unheard of. Bristol obtained FDA approval for Liso-cel ***415 days*** after its initial BLA filing—***more than twice the 194-day average*** time for FDA approval of similar therapies:

CAR-T Therapy	Manufacturer	BLA Submission Date	FDA Approval Date	Days from BLA Submission Date to FDA Approval
Liso-cel	***Bristol***	***12/19/2019***	***2/5/2021***	***415***
Tecartus	Gilead (Kite)	12/11/2019	7/24/2020	226
Kymriah	Novartis	3/28/2017	8/30/2017	155
Yescarta	Gilead (Kite)	3/31/2017	10/19/2017	202

¶ 137. Bristol's approval time was nearly ***double*** the average time for FDA approval for the other nine therapies Bristol and Celgene submitted for approval between July 2014 and 2020 (221.6 days); and ***49 days longer*** than ***any*** of the other 9 drugs approved by the FDA during the same time frame, despite the fact that Liso-cel had the benefit of being a designated Breakthrough Therapy and a Regenerative Medicine Advance Therapy with Priority Review status:

[9] Celgene submitted the complete FDA approval application for Ozanimod, the third Milestone Drug, well before the merger closed and Bristol took control of the process. ¶ 95.

Original NDA and Original BLA Approvals Filed By Bristol and Celgene, 2014-2020				
Applicant	**Proprietary Name**	**FDA Received Date**	**Approval Date**	**Days from FDA Received Date to Approval Date**
Bristol	Opdivo	7/30/2014	12/22/2014	145
Bristol	Evotaz	4/4/2014	1/29/2015	300
Bristol	Daklinza	3/31/2014	3/4/2015	338
Bristol	Empliciti	6/29/2015	11/30/2015	154
Celgene	Idhifa	12/30/2016	8/1/2017	214
Celgene	Reblozyl	4/4/2019	11/8/2019	218
Celgene	Zeposia	3/25/2019	3/25/2020	366
Celgene	Onureg	3/3/2020	9/1/2020	182

¶¶ 32, 82, 138-42. Liso-cel was approved 81 days after its amended target approval date, and 171 days after its original target approval date, ***even though Priority Review drugs are nearly always approved by the target date***. ¶ 97. Over 9,000 lymphoma patients died in those 171 days. ¶ 131.

Bristol then lied to investors about the reason for the delay, claiming it missed the milestone date due to "Covid-related inspection delays." ¶ 153. Bristol's competitor, Gilead, submitted a BLA for a similar drug, Tecartus, to the FDA eight days prior to Liso-cel's submission. ¶ 138. Tecartus was approved almost ***six months faster*** than Liso-cel. ¶ 138. If Bristol had used the same diligent efforts as Gilead, it would have made the Liso-cel deadline by 153 days. ¶ 138.

For Bristol's finances, the near-miss of the Liso-cel milestone was perfect: it allowed Bristol to avoid the $6.4 billion payout to the CVR holders ***yet*** benefit from Liso-cel's approval about a month after the milestone date. ¶¶ 6, 130. The near-miss also proved lucrative for the Individual Defendants, who held millions of dollars' worth of Bristol stock that became significantly more valuable once Bristol avoided the CVR payouts. *See infra* § I.B.

As they slow-rolled Liso-cel's approval, Defendants repeatedly made materially false and misleading statements concerning the "***diligent efforts***" Bristol was purportedly making to secure Liso-cel's approval by the milestone date, the likelihood of securing approval by that date, and the purported value of the CVRs. ¶¶ 8, 28, 88, 155-206. Additionally, Defendants repeatedly allayed

investors' concerns about the CVR payouts and suggesting the approval process was proceeding apace without significant issue—with the exception of the potential impact of COVID-19—without disclosing they were in fact intentionally delaying the process. ¶¶ 168-207.

Plaintiffs brought this federal securities action on behalf of all persons who acquired CVRs pursuant to the merger and from November 20, 2019 through December 31, 2020, asserting claims under Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 ("Securities Act") and Sections 10(b), 14(a), 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act").

LEGAL STANDARDS FOR A MOTION TO DISMISS

On a Rule 12(b)(6) motion, courts accept the factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Alaska Elec. Pension Fund v. Bank of Am. Corp.*, 175 F. Supp. 3d 44, 52 (S.D.N.Y. 2016). A complaint need only "state a claim to relief that is plausible on its face" to survive. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

"The Second Circuit and district courts in this circuit routinely rely on expert and statistical analyses contained in pleadings." *In re Platinum & Palladium Antitrust Litig.*, 2017 WL 1169626, at *13 n.9 (S.D.N.Y. Mar. 28, 2017) (collecting cases). The complaint may "rely on confidential sources," including confidential witnesses or confidential experts "'described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged.'" *In re Ambac Fin. Grp., Inc. Sec. Litig.*, 693 F. Supp. 2d 241, 283 (S.D.N.Y. 2010) (quoting *Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000)); *see also Sjunde AP-Fonden v. Gen. Elec. Co.*, 2021 WL 311003, at 8, 11, 12 (S.D.N.Y. Jan. 29, 2021) (Furman, J.) (considering assertions offered by non-party former employees); *Sjunde AP-Fonden v. Gen. Elec. Co.*, 417 F. Supp. 3d 379, 409, 413–14 (S.D.N.Y. 2019) (Furman, J.)

(upholding claims based on assertions by former employees). The court may only consider documents outside the complaint if "attached to the complaint, incorporated in it by reference, integral to the complaint, or the proper subject of judicial notice." *United States v. Strock*, 982 F.3d 51, 63 (2d Cir. 2020) (quotation marks omitted).

ARGUMENT

I. THE COMPLAINT PLEADS A STRONG INFERENCE OF SCIENTER.

The Complaint raises a strong inference of scienter that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent," *Tellabs Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007), because it pleads both "strong circumstantial evidence of conscious misbehavior or recklessness" and that Defendants had a "motive and opportunity to commit fraud" —either of which is sufficient on its own to plead scienter, *Set Cap. LLC v. Credit Suisse Grp. AG*, 996 F.3d 64, 78 (2d Cir. 2021).

A. The Complaint Alleges Strong Circumstantial Evidence That Defendants Deliberately Delayed FDA Approval to Avoid Paying $6.4 Billion.

1. The Most Plausible Explanation for the Repeated Delays Caused by Bristol is Deliberate or Reckless Intent.

When Bristol took over Celgene, Liso-cel and the other Milestone Drugs were "on track" for approval prior to their milestone dates, with Liso-cel scheduled for approval 4.5 months before its milestone date. ¶ 92-93, 98. When Bristol took over the FDA approval process for the Milestone Drugs, however, it suddenly and inexplicably went off the rails. Coincidence? Hardly.

First, Bristol took ***29 days*** after taking over Celgene to submit the Liso-cel BLA's CMC module, a delay the FDA Biologics Expert confirmed was "unusually" long. ***Second***, despite this unusual delay, the CMC module inexplicably failed to include the underlying assay data Bristol had in its possession. ¶¶ 33, 99. According to the FDA Biologics Expert, a company diligently seeking approval of a biologic would not have omitted such assays from its BLA submission and

would have understood those omissions could significantly delay FDA approval. ¶ 99. ***Third***, when the FDA asked for the missing data, Bristol did not provide it for ***23 more days***—a delay the FDA Biologics Expert described as "highly unusual" since Bristol certainly had the data. ¶ 100. ***Fourth***, Bristol's late submission of the required CMC data predictably caused further delay—a Major Amendment that triggered a ***90-day delay*** of the target approval date. ¶ 102. This was a development the FDA Biologics Expert called the "rarest of rare occurrences" for a Priority Review cancer therapy, and which CW #1 stated he or she had never before seen despite years of industry experience. ¶ 101. ***Fifth***, and ***after*** that occurred, Bristol submitted the BLA for Ide-cel, the third Milestone Drug, with a facially incomplete CMC module, causing the FDA to push Ide-cel's target approval date right up against its March 31, 2021 milestone date. ¶ 211. According to the FDA Biologics Expert, these unusual deficiencies would have been obvious to any pharmaceutical executive responsible for submitting biologics to the FDA for approval. ¶¶ 20, 22.

But there's more. ***Sixth***, the FDA identified myriad problems at Bristol's Juno manufacturing facility. According to the FDA Biologics Expert and multiple CWs, these were obvious, easily preventable issues that should have been avoided by a normally competent company familiar with biologics. ¶¶ 107-112. Predictably, the FDA issued a Form 483 identifying these deficiencies. ***Seventh***, Bristol took ***21 days***—the ***maximum allowed***—to respond to the Form 483, even though this could have easily been done in ten days, per the FDA Biologics Expert. ¶ 113. ***Eighth***, Bristol's response itself was found deficient by the FDA, yet Bristol did not properly supplement it until less than two weeks before the Liso-cel milestone deadline. ¶ 114.

Ninth, the FDA identified ***many of the same or similar*** errors at the Lonza facility for Liso-cel. ¶¶ 115-16. That is, the FDA identified these easily identifiable and fixable errors at Juno and, instead of fixing them at Lonza, Bristol left them unremedied for the FDA inspection at Lonza.

¶¶ 115-16. Moreover, according to a number of former Lonza employees, these problems were obvious and Bristol employees were aware of them—but did not fix them in advance of the FDA inspection. ¶¶ 120-21, 125. And ***tenth***, Bristol's responses to the FDA's deficiency letter on Lonza was also found deficient and required supplementation. According to the FDA Biologics Expert, it is "rare and contrary to standard industry practice for an initial response to a Form 483 to be insufficient—and even rarer . . . for a second response to also be insufficient." ¶ 126.

After these ten—***ten!***—events, each one highly unusual for a large, sophisticated, and experienced drug company, and each of which delayed the FDA approval process,[10] Liso-cel's milestone date passed and Bristol avoided the $6.4 billion payout. Liso-cel was approved 36 days later, dramatically improving Bristol's financial condition while minimizing its negative exposure.

Defendants imply that these ***ten*** highly unusual events—***all*** of which caused delays in the exact drugs whose rapid FDA approval would trigger a massive liability for Bristol—were random, unexpected coincidences. One coincidence makes sense, two coincidences can happen—but it is simply implausible that these ten events all happened in such a way as to delay the FDA approval of Liso-cel just enough to save Bristol $6.4 billion, ***accidentally***.

"As is the case with all motions to dismiss, plaintiffs are entitled to all reasonable factual inferences that logically flow from the particularized facts alleged." *In re Veeco Instruments, Inc.*

[10] Even ignoring the 90-day delay due to the Major Amendment Acknowledgement, Defendants' other dilatory tactics alone amount to nearly double the amount of time by which they missed the Celgene milestone date. First, Bristol took 29 days after taking over Celgene to submit Liso-cel's BLA's CMC module. Second, Bristol took another 23 days to supplement its deficient submission to the FDA. Third, Bristol took 21 days—the maximum allowed—to respond to the FDA's first Form 483, when it could have done so in a mere 10 days, thereby delaying the approval process another 11 days. These three delays alone amount to a total of 63 days—nearly double the 36-day mark by which Bristol missed its milestone deadline. Thus, it is apparent Bristol did not use diligent efforts (as defined in the Joint Proxy, ¶¶ 16, 88) to achieve the CVR milestones. At a minimum, this is a factual issue that cannot be decided on this motion.

Sec. Litig., 434 F. Supp. 2d 267, 274 (S.D.N.Y. 2006). Here, the far more plausible inference is that this series of highly atypical failures—all of which delayed but did not derail FDA approval—were intentionally designed to accomplish just that. ***No other comparable drug*** in recent memory has experienced such avoidable delays in the FDA approval process, including all other Bristol and Celgene drugs approved in the past eight years (which suggests Bristol is perfectly competent at securing timely approval when it wants)—not Liso-cel's competitor Tecartus, not any other comparable drug. ¶¶ 137-42. This inference is "at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314; *see also In re Scottish Re Grp. Sec. Litig*., 524 F. Supp. 2d 370, 381, 394 n.176 (S.D.N.Y. 2007) ("highly unusual and suspicious facts" "add to the overall pleading of circumstantial evidence of fraud"); *In re BioMarin Pharm. Inc. Sec. Litig.*, 2022 WL 164299 at *13 (N.D. Cal. Jan. 6, 2022) (scienter found where defendants "told the market that they had high confidence in approval on the set timeline and had a good relationship with the FDA when in fact there were allegedly concrete warning signs otherwise").

Defendants do not really attempt to justify their repeated and highly unusual delays. Instead, they make two legally unsupportable arguments that can easily be rejected. First, they argue the Court should disregard the allegations provided by the FDA Biologics Expert because "[c]ourts regularly reject such allegations." DB 17. This is wrong. "The Second Circuit and district courts in this circuit routinely rely on expert and statistical analyses contained in pleadings." *In re Platinum*, 2017 WL 1169626, at *13 n.9 (collecting cases); *see also Sjunde AP-Fonden*, 2021 WL 311003, at *8 (using expert's findings not inappropriate in complaint); *Ambac*, 693 F. Supp. 2d at 283 (sustaining pleadings and approving use of confidential expert testimony). This is especially so where—like here—the expert is utilized for explanatory and clarification purposes and is supported by specific rules and regulations on which their opinion is based, rather than to offer

conclusory testimony on a central issue in the litigation.[11]

Defendants argue this common practice is forbidden, DB 17 & 25 n.12, but their own case citations show why that argument fails here, where the FDA Biologics Expert's non-conclusory assertions are alleged in the ***body of the complaint***. *See Ong v. Chipotle*, 294 F. Supp. 3d 199, 222 (S.D.N.Y. 2018) (court "will consider well-pleaded factual allegations [in the complaint] that cite to the [d]eclaration"); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1222 (S.D. Cal. 2001) ("[a] better approach might be to include the expert's nonconclusory assertions within specific paragraphs of the complaint"). Indeed, the inclusion of the FDA Biologics Expert's assertions in the complaint is no different than using CWs to serve a similar purpose, which this Court also regularly allows. *See, e.g.*, *Ambac*, 693 F. Supp. 2d at 283 (noting that plaintiffs can "rely on confidential sources," including CWs or confidential experts, "provided they are 'described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged'" (quoting *Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000))). Here, Plaintiffs' expert is well-qualified, having previously worked for the FDA as a senior reviewer and investigator for its Center for Biologics Evaluation and

[11] While courts are free to disregard expert assertions that amount to conclusory legal opinions, none are offered here. *Cf. In re Commodity Exchange, Inc.*, 213 F. Supp. 3d 631, 666 (S.D.N.Y. 2016) ("The Court is not . . . relying on Plaintiffs' opinions (expert or otherwise) but rather on Plaintiffs' factual assertions regarding pricing and other economic data . . . ."). The FDA Biologics Expert did not offer legal opinions on the issues before the Court. Rather, Plaintiffs' FDA Biologics Expert offered clarification on the following factual points: which FDA inspection deficiencies are considered "basic," ¶¶ 5, 109-112, 121-25; which BLA requirements are most important, ¶¶ 20, 22, 100; the exceptional nature of Major Amendment Acknowledgements, ¶¶ 23, 101; the general timeline for submission of various sections of the BLA, ¶¶ 96, 100; the standard practices that go into preparing a facility for inspection, ¶¶ 108, 115-16, 120; and what FDA Form 483 responses are obviously deficient or untimely, ¶¶ 113-14, 126, 214. As such, at this stage the Court must accept them as true, just as it would any other well-pleaded allegation. Further, the FDA Biologics Expert's assertions are thoroughly sourced to specific regulations and other regulatory materials, which shows they are designed to aid a layperson in understanding difficult subject matter—and not to provide impermissible opinions on legal subjects at issue in the case.

Research, ¶ 4, and offers only non-speculative[12] fact-based explanation on industry regulation and practice to supplement the allegations in Plaintiffs' complaint.

Second, Defendants say the Court should disregard allegations from former employees of Lonza, which ran a Liso-cel manufacturing facility, because they were not Bristol employees. *See* DB 10. This makes no sense. Courts regularly credit CWs who are not former defendant employees, as long as—like here—they were in a position to know. *See, e.g., Ambac*, 693 F. Supp. 2d at 283; *Kuriakose v. Fed. Home Loan Mortg. Corp.*, 2011 WL 1158028, at *6 (S.D.N.Y. Mar. 30, 2011) (relying on "a former employee of [the regulatory body overseeing defendant]" in sustaining pleading); *In re SCANA Corp. Sec. Litig.*, 2019 WL 1427443 (D.S.C. Mar. 29, 2019) (relying on third-party CW in sustaining pleading); *Mass. Mut. Life Ins. Co. v. Residential Funding Co.*, 843 F. Supp. 2d 191, 201 n.6 (D. Mass. 2012) (same); *Cap. Ventures Int'l v. UBS Sec. LLC*, 2012 WL 4469101, at *4 (D. Mass. Sept. 28, 2012) (same). Likewise, that CW #1 is not alleged to have interacted with Bristol executives, DB 33, does not undermine CW #1's view, based on industry experience and involvement in Liso-cel's approval process, that the Major Amendment was an unusual and avoidable "major blunder." ¶ 101.

Defendants also argue that CW #2's and CW #3's statements support the inference that Bristol was working diligently to obtain approval for Liso-cel by the milestone date. DB 25-26, 33. In fact, they do the reverse—they show that Bristol was aware of the issues at the Lonza facility, was told that their timeline was unreasonable, didn't provide sufficient resources to the facility, and refused to adapt to the situation by not fixing and concealing the problems from

[12] Although an expert's opinion cannot be used to overcome contradictory facts alleged elsewhere in the complaint, *see Ark. Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 351, 354 (2d Cir. 2022), such a concern is inapplicable here, where the expert's statements harmonize with and bolster Plaintiffs' other factual allegations.

investors, instead saying the facilities were "launch ready." *See* ¶¶ 106, 120-22.

2. Defendants' Concealment of the Fraud is Probative of Scienter.

In developing and seeking approval of a new drug, there is scienter if "management knows that certain facts will necessarily prevent the regulatory approval" and "conceals these facts from the investing public." *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008); *see also Woods v. Maytag Co.*, 807 F. Supp. 2d 112, 126 (E.D.N.Y. 2011) (defendants' "attempt to conceal the problem" indicated scienter). Similarly, there is scienter if "management is reckless in dealing with such adverse facts." *AstraZeneca*, 559 F. Supp. 2d at 470. This is exactly what the Complaint alleges Defendants did, though the intent was to delay, not prevent, approval.

First, during the Class Period, Defendants repeatedly and falsely placed the blame for the repeated delays of the Liso-cel BLA approval process on COVID-19–related plant inspection delays—excuses they echo now in their briefing. ¶¶ 32-33, 153, 220; DB 2, 8, 32-33. But this is false. In 2020, the FDA approved 53 novel drugs, the second highest number in two decades, including 20 cancer drugs and 13 biologics. ¶¶ 153, 220. Bristol's competitor Gilead secured FDA approval of Liso-cel's rival therapy Tecartus ***189 days faster*** than it took Bristol for Liso-cel—even though Gilead submitted the Tecartus BLA ***just one week*** before Bristol submitted Liso-cel's, during the ***same*** COVID-19 pandemic that in Defendants' telling delayed BLA approvals. ¶¶ 138-40. Defendants' statements about the impact of the COVID-19 pandemic on the Liso-cel approval timeline were an attempt to conceal their fraud, and probative of scienter. *Cf. BioMarin*, 2022 WL 164299, at *11 n.7 (disregarding, at the motion to dismiss stage, defendants' "argument that COVID-19 caused the FDA's delay in the inspection").

Second, Defendants concealed their fraud by falsely representing that Bristol's top executives had strong financial incentives to secure Liso-cel's timely approval. ¶¶ 143-51. In March 2020, Bristol stated its executives' compensation packages "align[] our executives'

interests with our shareholder outcomes, including those shareholders holding CVRs," and that "the 2020 pipeline goal will take into account the specific [CVR] milestones." ¶ 145. This was false—the CVR milestones ***did not meaningfully affect*** the executives' compensation. ¶¶ 147-49.

B. The Complaint Alleges a Motive for Defendants' False and Misleading Statements: Avoiding the Massive $6.4 Billion CVR Payout

Although "personal pecuniary motive is not required to plead scienter," *Freudenberg v. E*Trade Fin. Corp.*, 712 F. Supp. 2d 171, 200 (S.D.N.Y. 2010), Plaintiffs sufficiently allege it here. Defendants' motive was to avoid the massive $6.4 billion payout by Bristol to the CVR holders. This payout was nearly as much as Bristol's entire $7.0 billion in net earnings in 2021, following a year in which Bristol lost $9.0 billion, ¶¶ 150, 221, and an amount so massive it is probative of scienter on its own, *see In re Salix Pharms., Ltd.*, 2016 WL 1629341, at *16 & n.15 (S.D.N.Y. Apr. 22, 2016) (collecting cases for the proposition that the magnitude of the fraud provides circumstantial evidence of scienter).[13] Moreover, not paying the $6.4 billion to CVR holders allowed Bristol to pay down $4 billion of debt earlier than scheduled. ¶ 152.

Defendants' ulterior motives from the start of the Class Period are confirmed by Bristol's suspect insistence on an atypical all-or-nothing CVR payout structure, without which Bristol's plan would not have worked because each missed milestone date would only have saved Bristol $2 per share. ¶ 14. They are also confirmed by Bristol's highly suspicious refusal to buy back any CVRs on the open market during a period in which Bristol was publicly claiming all three drugs were on track for approval and the CVRs were trading well below the $9 payout (between $0.61

[13] Defendants argue that they cannot have acted with scienter because deliberately slow-rolling Liso-cel's approval would expose them to "the risk of a breach of contract claim." DB 30. Defendants' argument is "an individual cannot intentionally or recklessly commit securities fraud because there may be negative consequences for committing securities fraud." People break the law all the time, despite the risk of getting caught.

and $4.76 during the Class Period), such that buying back CVRs could have saved Bristol a huge sum of money in avoided payouts. ¶ 94. The most logical inference is that Bristol knew its delaying tactics would eventually render the CVRs worthless, so it made no economic sense for Bristol to buy back any CVRs. On the other hand, during this time period, Bristol made numerous buybacks of its common stock, belying any claim that Bristol could not afford to repurchase CVRs or was reluctant to do so because of asymmetric information, as it claimed. ¶ 218.

The Individual Defendants were also motivated by increases in the value of their millions of dollars' worth of Bristol common stock. ¶¶ 151, 221. According to analysts at Guggenheim Partners, avoiding the $6.4 billion CVR payouts was worth ***5% of Bristol's total value*** and ***$3 per share***—enough to significantly increase the value of these holdings. ¶ 150. Indeed, in the 15 days following its announcement on January 1, 2021 that the CVR agreement had terminated, Bristol's stock price rose from around $61 to around $67.[14] Moreover, Bristol did not tell investors that the executive Defendants' compensation packages depended heavily on Bristol's stock performance, but were not dependent on the CVR milestones because the executives could score well on the "pipeline" factor simply by making a large number of regulatory submissions and approvals, even without securing Liso-cel's timely approval—which is exactly what they did, entitling them to approximately $5.9 million in incentive award payouts despite the delays. ¶¶ 148-49.

Defendants argue that the fact that they did not engage in stock sales during the Class Period cuts against an inference of scienter. DB 29-31. This is backwards. Unlike the cases cited by Defendants, this case concerns artificial inflation of the ***CVRs*** (which Defendants did not own[15]), not the defendant company's ***common stock*** (which Defendants did own). Here, it made

[14] *See* https://finance.yahoo.com/quote/BMY/history?p=BMY.

[15] Defendants claim that "many former Celgene officers and employees who continued in their

more sense for Defendants ***not*** to have sold their Bristol common stock during the Class Period, because they knew that stock would become more valuable when the CVRs expired at the ***end*** of the Class Period (as noted, the stock price increased from $61 to $67 in the two weeks after the Class Period when the CVRs expired worthless). Defendants' incentive was to maximize the share price of Bristol's common stock by avoiding the CVR payouts. The Individual Defendants thus had strong personal motives to prevent CVR payouts, which is probative of scienter.

C. The Individual Defendants Were Directly Involved with and Responsible for the CVR Milestone Process and Corporate Scienter is Adequately Pled.

Allegations that Defendants "knew facts or had access to information suggesting that their public statements were not accurate" or "failed to check information they had a duty to monitor" support a strong inference of scienter. *Novak*, 216 F.3d at 311; *see also In re Inv. Tech Grp., Inc. Sec. Litig.*, 251 F. Supp. 3d 596, 621 (S.D.N.Y. 2017) (knowledge or access to information showing public statements to be inaccurate "alone" is enough to satisfy scienter).

Here, Defendants Caforio and Bancroft[16] told analysts from Guggenheim Partners, an investment firm, that "oversight of the CVR is a board-level responsibility and BMY [Bristol] is highly motivated to pay out the CVR" and that "BMY has no plans to buy back the CVR early . . . because of the availability of asymmetric information available to BMY vs. the shareholders of the CELG CVR." ¶¶ 92, 166, 210. The Complaint further alleges that Bristol's top management repeatedly made false or misleading statements about the status of the FDA review process, the alleged progress being made and Bristol's efforts to meet the target approval dates. *See, e.g.*,

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roles for the FDA approval process were holders of CVRs that they received in the merger." DB 31. But none these individuals had ultimate authority or responsibility for the timing of Bristol's BLA submissions for Liso-cel, and none are Individual Defendants.

[16] Defendant Bancroft was Bristol's Chief Financial Officer prior to being replaced by Defendant Elkins in June 2019. ¶ 62.

¶¶ 181, 183, 185-86, 188, 191, 193, 195. This means they either knew about the undisclosed issues with Liso-cel's FDA approval process, or "failed to check information they had a duty to monitor." *Novak*, 216 F.3d at 311. Given these representations and Liso-cel's importance to Bristol, it is "exceedingly unlikely" Defendants' false or misleading statements resulted from mere "careless mistakes at the management level" rather than intentional deception or "reckless indifference" to the truth. *Makor Issues & Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702, 809 (7th Cir. 2008).[17]

The Complaint's extensive allegations about Defendants' "egregious refusal to see the obvious or to investigate the doubtful," *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 269 (2d Cir. 1996), bolster the inference of scienter raised by these allegations, *see, e.g.*, *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1130 (C.D. Cal. 2005) (nature of problems identified in Form 483 "raise[d] a strong inference" that defendants "had actual knowledge that these problems could delay or jeopardize" FDA approval). For example, the Liso-cel BLA's CMC module lacked so much important information that supplementing it led the FDA to issue a Major Amendment and push the target approval date back three months.[18] CW #1 stated he had never before seen this sequence of events despite being involved in FDA approval of 12–13 different drugs, and the FDA Biologics Expert called it the "rarest of rare occurrences" for a Priority Review cancer therapy. ¶ 101. Bristol

[17] *See also Miss. Pub. Emps. Ret. Sys. v. Bos. Sci. Corp.*, 523 F.3d 75, 91-92 (1st Cir. 2008) (speaker was company's "point person" on product and "would presumably have been aware" of company's monitoring of same); *MannKind*, 835 F. Supp. 2d 797, 815 (C.D. Cal. 2012) (company's interactions with FDA regarding drug approval "were absolutely integral to the company's success, and it would therefore be absurd to suggest that management was without knowledge of the matter").

[18] Defendants' brief improperly cites evidence outside the pleadings to suggest that the FDA's Major Amendment decision may have been due to the FDA's purported inconsistency in reviewing cell therapy applications. DB 9 (citing ECF No. 101-3). But the exhibit Defendants cite says nothing about Major Amendments or Liso-cel. And Defendants do not actually dispute the Liso-cel Major Amendment was triggered by one thing: Bristol's failure to submit data it knew it should have submitted in its original application.

then submitted the BLA for Ide-cel, another of the three Milestone Drugs, with a CMC portion that was ***also*** facially incomplete, causing the FDA to push Ide-cel's target approval date right up against its March 31, 2021 milestone date. ¶ 211. According to the FDA Biologics Expert, these deficiencies would have been obvious to ***any*** pharmaceutical executive who was responsible for submitting biologics for FDA approval, and ***certainly*** well known to Bristol's. ¶¶ 20, 22.

The Complaint also adequately pleads corporate scienter. As set forth above, the Complaint pleads sufficient facts to create a strong inference that the Individual Defendants, whose intent can be imputed to Bristol, acted with the requisite scienter. The Complaint also pleads sufficient facts to demonstrate that the Individual Defendants approved or themselves made the false and misleading statements at issue and knew those statements were misleading. *See Lorely Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 177 (2d Cir. 2015).

D. <u>The Complaint Does Not Allege Fraud-by-Hindsight.</u>

Defendants argue this case concerns fraud-by-hindsight, implying that they could not have foreseen that Liso-cel's approval would be delayed when they made the alleged misrepresentations. This is false. Plaintiffs allege Defendants ***knew***, from as early as February 20, 2019, when they successfully demanded an atypical "all-or-nothing" CVR structure, ¶ 15, that the Liso-cel CVRs ***would be*** worthless, and ***caused*** them to be worthless by deliberately delaying FDA approval. Such a "secret plan" is meaningfully different from fraud-by-hindsight. *See Friedman v. Endo Int'l PLC*, 2018 WL 446189, at *6 (S.D.N.Y. Jan. 16, 2018) (plaintiffs alleged fraud-by-hindsight ***and not*** "a secret plan" to change pharmaceutical company's business model). The Complaint extensively alleges that any pharmaceutical company executive in Defendants' shoes would have known that Bristol's conduct would cause Liso-cel to miss the milestone date. ¶¶ 5, 20, 22, 30, 96, 99, 100, 112-14. In any event, this argument has no bearing on Plaintiffs' strict-liability Securities Act claims, which by definition have no foreseeability requirement.

II. SCIENTER IS NOT REQUIRED FOR PLAINTIFFS' SECTION 14(a) AND SECURITIES ACT CLAIMS.

While the Complaint does adequately plead a strong inference of scienter, scienter is not a requirement for claims brought under Section 14(a) of the Exchange Act, which are brought under a negligence standard, or claims brought under Sections 11, 12(a)(2), and 15 of the Securities Act, which are brought under a strict liability standard.[19] Defendants' argument that the Securities Act claims sound in fraud, DB 21 & n.10, is particularly misguided with respect to the Signer Defendants,[20] who are not alleged to have acted fraudulently, but to have failed to conduct a reasonable investigation before signing and issuing Bristol's SEC disclosures—placing them in the same position as an auditor or underwriter subject to strict liability or a negligence standard.[21]

III. THE COMPLAINT ALLEGES FALSE AND MISLEADING STATEMENTS.

Defendants claim the Complaint does not allege false and misleading statements. DB 13-21, 23-29. They are wrong. "The test for whether a statement is materially misleading . . . is

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[19] *See, e.g., Rombach v. Chang*, 355 F.3d 164, 168 n.4 (2d Cir. 2004) ("Neither [§] 11 nor [§] 12(a)(2) requires that plaintiffs allege the scienter . . . element[] of a fraud cause of action."); *Enzo Biochem, Inc. v. Harbert Discovery Fund, LP*, 2021 WL 4443258, at *8 (S.D.N.Y. Sept. 27, 2021) ("It is well established in this circuit that scienter is not a required element of a Section 14(a) claim."); *Ho v. Duoyuan Global Water, Inc*., 887 F. Supp. 2d 547, 562 (S.D.N.Y. 2012) (scienter not an element of a § 15 claim).

[20] Vicki L. Sato, Peter J. Arduini, Robert Bertolini, Matthew W. Emmens, Michael Grobstein, Alan J. Lacy, Dinesh C. Paliwal, Theodore R. Samuels, Gerald L. Storch, Karen H. Vousden, Charles Bancroft, and Karen M. Santiago.

[21] *See, e.g., Ambac*, 693 F. Supp. 2d at 275 (Securities Act claims against auditor and underwriters "do not sound in fraud" because complaint "does not allege [they] acted fraudulently"); *In re WorldSpace Sec. Litig.*, 2008 WL 2856519, at *4-5 (S.D.N.Y. July 21, 2008) (Securities Act claims subject to Rule 8(a) where defendants allegedly owed plaintiffs duty to make "reasonable and diligent investigation" and offering documents "negligently prepared").

Defendant Caforio is the only Individual Defendant other than the Signer Defendants against whom Plaintiffs assert claims under the Securities Act or Section 14(a) of the Exchange Act. Although Plaintiffs are not required to plead scienter for these claims, it is nevertheless sufficiently pled as to Defendant Caforio. *See supra* § I.

not whether the statement is misleading in and of itself, but whether the defendants' representations, taken together and in context, would have misled a reasonable investor," *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 250 (2d Cir. 2016) (quotation marks omitted), or "significantly alter[ed] the total mix of information made available," *Set Cap.*, 996 F.3d at 84.[22]

Here, starting with the February 22, 2019 Joint Proxy and continuing for nearly 21 months, Defendants made numerous false and misleading statements about how Bristol (1) was on track and working diligently to achieve FDA approval before the milestones, (2) was motivated to pay out the CVRs, and (3) that its failure to meet the milestone was caused by COVID.[23] These statements were false or misleading because, *inter alia*, they omitted Bristol's deliberate decision to slow-roll the Liso-cel (and Ide-cel) approval process to ensure that the milestones would never be met, and that it was those delays—not the COVID-19 pandemic—that caused Bristol to blow the CVR deadline. *See, e.g.*, *Warshaw v. Xoma Corp.*, 74 F.3d 955, 957-60 (9th Cir. 1996) (statements about timing of FDA approval actionable under § 10(b) due to failure to disclose issues that could delay approval by months); *In re MannKind Sec. Actions*, 835 F. Supp. 2d at 804, 811-12 (statements that "implied that there would be no serious impediments to timely FDA approval" false and misleading where defendants failed to disclose potential issues with clinical trials that could delay FDA approval); *Yanek*, 388 F. Supp. 2d at 1130 ("Defendants' omission of facts suggesting a possible delay in [FDA] approval was misleading"). *In re BioMarin* is instructive. There, because "BioMarin was allegedly aware of concrete risks that approval would be denied

[22] Defendants repeatedly attempt to import a new requirement into the § 10(b) falsity standard: that the speaker knew the statement was false or misleading when made. *See* DB 16, 20, 24, 25. This argument confuses the issues of falsity (which does not take into account a defendant's state of mind) and scienter (which does).

[23] The appendix to Defendants' brief purports to summarize the allegedly false or misleading statements. Ironically, the appendix misrepresents the misrepresentations by omitting portions that provide crucial context. *Compare* DB App'x 1 *with* ¶¶ 166, 181, 185, 191, 193, 195, 201, 202.

even as it projected that it would be granted," its "[s]tatements to that effect are plausibly misleading." 2022 WL 164299 at *10. So too here.

A. Defendants Hid Their Plan To Deliberately Delay the FDA Approval Processes for Liso-cel and Ide-cel and Avoid the $6.4 Billion CVR Payouts.

Defendants made numerous statements that were false or misleading because they omitted that Bristol intended to or did deliberately delay the FDA approval process for Liso-cel (and Ide-cel) to avoid the CVR payouts. ¶¶ 158, 160-61, 163-64, 166, 169, 171, 173, 176, 179, 181, 183, 185-86, 188, 190-91, 193, 195, 198, 201-02, 205. For instance, the Joint Proxy stated:

1. there was a strong possibility the Liso-cel milestone would be met and Bristol would in good faith use diligent efforts to meet it, ¶ 158;

2. Liso-cel was "expected to launch in 2019 and 2020," ¶ 158; and

3. Bristol would use "'diligent efforts' to achieve the CVR milestone," ¶ 161.

Defendants repeatedly assured investors Bristol was committed to making Liso-cel available to patients "as soon as possible," ¶¶ 181, 191, 195, 201-02, and was "continu[ing] to advance [its] regulatory filings" for Liso-cel and Ide-cel by "working actively with the FDA to keep the review and the inspection process moving," and "working with the FDA to progress both applications and achieve the remaining regulatory milestones," ¶¶ 173, 176, 195, 205. Caforio and Hirawat ***specifically*** represented that "[a]chievement of key milestones associated with the . . . CVR is on track" and Bristol was "continu[ing] to meet our CVR milestones." ¶¶ 166, 181. And on seven separate occasions between May 7, 2020 and September 17, 2020, Caforio and Hirawat discussed the status of the FDA review process, talked about their awareness of the delays and the site inspections, and stated Bristol was "looking forward to" and "keep[ing] on" Liso-cel's November 2020 target approval date and planned to secure Liso-cel's approval by "the end of the year [(*i.e.*, 2020)]." ¶¶ 181, 183, 186, 190, 191, 193, 195. These statements were false or misleading because Bristol never intended to and never did use diligent efforts to meet all the CVR

milestone deadlines, that the milestones were not being met due to Bristol's multiple errors which were part of its delaying tactics, and in fact it intended to and did deliberately delay the FDA application process for Liso-cel (and Ide-cel) so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment. ¶¶ 159, 162, 165, 167, 170, 172, 174, 177, 180, 182, 184, 187, 189, 190, 192, 194, 196, 199, 203, 206. Defendants' arguments to the contrary fail.

First, Defendants argue their statements about the FDA approval processes for the Milestone Drugs are inactionable because they were not ***literally false***. *See* DB 23-24. This argument fails. First, their statements were ***literally false***. Defendants' statements reinforced that Bristol was working to ensure FDA approval of the Milestone Drugs by their milestone dates when Defendants were working to ensure that did ***not*** happen. Second, "the disclosure required by the securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead." *In re Mindbody, Inc. Sec. Litig.*, 489 F. Supp. 3d 188, 208 (S.D.N.Y. 2020) (quoting *McMahan & Co. v. Wherehouse Entm't, Inc.*, 900 F.3d 576, 579 (2d Cir. 1990)). These statements misled investors into believing that Bristol was diligently seeking FDA approval. Third, whether Bristol was or was not diligent is a factual issue that cannot be decided on this motion—and in any event, the facts alleged support an inference that Bristol did not act diligently.

Second, Defendants argue there is no "contemporaneous factual allegation to support the allegation that BMS intended to 'slow-roll' the FDA application process" when Defendants issued the Joint Proxy. DB 19. This is wrong for two reasons. First, Bristol's strange insistence during its negotiations with Celgene on the atypical "all or nothing" CVR provision prior to the issuance of the Joint Proxy makes the most sense if Bristol was, at that time, planning to delay FDA submission for at least one of the Milestone Drugs. Second, "[s]ubsequent acts are frequently probative as to intent," *United States v. Goffer*, 721 F.3d 113, 124 (2d Cir. 2013), and "[f]raud is almost always

detected after the fact, typically based on evidence developed subsequent to the allegedly fraudulent statements," *MannKind*, 835 F. Supp. 2d at 809. Defendants' steps to slow-roll Liso-cel's approval—starting after they issued the Joint Proxy, when they delayed submission of Liso-cel's CMC module—provide confirmation of their hidden intentions at the time they issued the Joint Proxy. *See, e.g.*, ¶¶ 4-6, 18, 20-25, 27, 95-96, 100-01, 103, 113-15, 126.

Third, Defendants argue their statements about working diligently and closely with the FDA to obtain approval of Liso-cel by year-end 2020 were mere "puffery," DB 28-29. But Defendants' claims were "undergirded by factual assertions such as timelines for approval and inspections," and therefore not puffery. *BioMarin*, 2022 WL 164299, at *12. Defendants' claims were also demonstrably relied upon by investors, and can be objectively verified both by reviewing the actions of Bristol with respect to Liso-cel approval as well as questioning Bristol employees about their actions, intentions, and communications.

B. Defendants Failed to Disclose They Deliberately Submitted Deficient Regulatory Submissions to Delay Liso-cel's and Ide-cel's Approval.

The Complaint alleges numerous statements that were false and misleading because they omitted to mention that Bristol was deliberately submitting deficient regulatory submissions for Liso-cel (and Ide-cel). ¶¶ 169-206; *see In re Nuvelo, Inc. Sec. Litig.*, 668 F. Supp. 2d 1217, 1230 (N.D. Cal. 2009) (plaintiffs sufficiently alleged a misrepresentation where the defendant knew the regulatory body would require different data and therefore that there was a material risk that the regulatory review would fail, but did not disclose that risk); *In re NPS Pharms., Inc. Sec. Litig.*, 2007 WL 1976589, at *4 (D. Utah July 3, 2007) (ruling that because "defendants knew and concealed" that "FDA approval of the drug [was] extremely unlikely," their statements were "not forward-looking predictions" but rather "knowing falsifications of historical fact").

C. Defendants Failed to Disclose They Did Not Adequately Prepare the Liso-cel Manufacturing Facilities for FDA Inspection.

Many of Defendants' alleged misrepresentations were false or misleading because they failed to disclose Bristol's inadequate preparations for FDA's inspections of Liso-cel's manufacturing facilities. ¶¶ 179, 181, 183, 185-86, 188, 190-91, 193, 195, 198, 201-02, 205. Most prominently, in September 2020, Caforio and Hirawat made a series of statements in which they explicitly referenced the upcoming inspections, stressed that "the importance of [the Liso-cel] application is very, very high for us," and assured investors they were working "to keep the review and the inspection process moving." ¶¶ 191, 195. Defendants' arguments to the contrary fail.

First, Defendants argue they had no duty to disclose Bristol's lack of readiness for the inspections. DB 26. This is wrong. The cases Defendants cite concern the disclosure of "interim FDA feedback," which "is not material because it does not express a binding agency decision." *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 542 (S.D.N.Y. 2015). The thread running through these cases is the defendant company's lack of control over or certainty about the FDA's ultimate decision. Here, Defendants failed to disclose something they had control over and knew for certain would delay the FDA approval process: their lack of preparation for the facility inspections.

Second, Defendants cite several cases that stand for the proposition that a company need not disclose every time it is accused of illegal activities. DB 26-27. These cases are inapposite because Plaintiffs do not allege Defendants failed to disclose wrongdoing.[24] Plaintiffs allege Defendants failed to disclose the facilities' lack of preparedness and issues later identified in the Forms 483, which were highly material to Liso-cel's ability to secure approval by the milestone

[24] Regardless, "a corporation's failure to disclose underlying unlawful conduct can be actionable" under § 10(b) "where affirmative statements were made misleading by the corporation's failure to disclose the alleged wrongdoing." *In re Mylan N.V. Sec. Litig.*, 379 F. Supp. 3d 198, 206 (S.D.N.Y. 2019).

dates. Defendants had a duty to disclose this information to "make the statements made, in the light of the circumstances under which they were made, not misleading." *See, e.g.*, *In re Vivendi*, 838 F.3d at 258; *see also McGuire v. Dendreon Corp.*, 2008 WL 5130042, at *4-8 (W.D. Wash. Dec. 5, 2008) (holding failure to disclose Form 483 and manufacturing facility deficiencies that could delay approval of BLA actionable under § 10(b)).

D. Defendants Misrepresented the Impact of the COVID-19 Pandemic on the Liso-cel Approval Process.

Starting in mid-2020, Defendants suggested the Liso-cel approval process was being held up by the COVID-19 pandemic. ¶¶ 179, 191, 195, 198, 201-02, 204. These statements were false and misleading because Defendants' actions, not COVID-19, were the cause of delay. The lack of COVID-19 impact was illustrated by Tecartus, a similar drug whose BLA was submitted at nearly the same time as Liso-cel's and during the same pandemic, but was approved ***six months faster than*** Liso-cel. ¶¶ 138-40, 180, 192, 194, 196, 199, 203, 206.

Defendants try to justify their false statements by blaming the delay on COVID-19, saying the "FDA had been inconsistent in its review of cell therapy applications" and citing a document outside of the complaint as support. *See* DB 9 (citing to *Pink Sheet* article entitled "Top US FDA Official Says New 'Playbook' Needed for CMC Review of Gene Therapy Projects"). This is wholly improper on a motion to dismiss as the document is extraneous to the pleadings and not a proper subject of judicial notice because it does not address matters that are generally known and not subject to reasonable dispute. *See* Fed. R. Evid. 201(b); *Strock*, 982 F.3d at 63. It is also factually irrelevant as the document says nothing about Liso-cel, Tecartus, or the difference in approval between the two. In any event, any purported COVID-caused delays, if true, of the FDA inspections cannot explain why Liso-cel missed its milestone deadline by 36 days. As explained above, Defendants' delay in submitting the CMC module and the missing CMC data alone

accounted for an at least 52-day delay ***and*** required postponing the inspections—COVID-related travel restrictions or not. Defendants' only excuse for falsely blaming the delay on COVID-19 is thus both legally impermissible and factually unsupported. *Cf. Reid v. Hemispherx Biopharma, Inc.*, 2010 WL 11710594 (E.D. Pa. Apr. 20, 2010) (statements claiming "FDA staffing problems" were to blame for delayed drug approval was false and misleading where delay was actually caused by company's failure to provide sufficient information to FDA on drug's safety and effectiveness).

E. Defendants Lied to Investors About Their Financial Incentives.

Defendants Caforio and Bancroft falsely told Guggenheim Partners, a financial advisory firm, that Bristol was "highly motivated to pay out the CVR because of the importance of the CELG pipeline to the company's future value" and that Bristol "has no plans to buy back the CVR early . . . primarily because of the availability of asymmetric information available to [Bristol]." ¶ 166. Defendants do not claim these statements were accurate. Rather, they argue that they cannot be held liable for the false statements under *Janus Capital Group Inc. v. First Derivative Traders*, 564 U.S. 135 (2011). DB 21 n.9. But *Janus* does not preclude liability for these statements, because they were explicitly attributed to members of Bristol's "[m]anagement" who attended the meeting on Bristol's behalf. *See, e.g.*, *Fragin v. Mezei*, 2012 WL 3613813, at *13 (S.D.N.Y. Aug. 22, 2012) (under *Janus*, "the person who initially provides the misleading information" is the "'maker' of that statement," even if the statement "passe[s] through an intermediary" to investors); *In re Allstate Life Ins. Co. Litig.*, 2012 WL 1900560, at *3 (D. Ariz. May 24, 2012) ("*Janus* did not abolish Rule 10b–5's restriction on misrepresentations made indirectly.").

F. The Alleged Misrepresentations Are Not Opinions, But Would Be Actionable Even If Wrongly Construed as Such.

Defendants argue BMS's statements that Celgene product candidates, including Liso-cel, were "expected to launch" by year-end 2020, that BMS estimated the probability of payment under

the CVRs to be 45%, and that there was "uncertainty regarding the fair market value of the CVRs and whether any payment will ultimately be realized," are inactionable opinion statements. DB 19. These are not opinions because Defendants knew and failed to disclose that Liso-cel would not launch by year-end 2020 and that there was a 0% chance the CVRs would pay out because Defendants were deliberately slow-rolling the Liso-cel approval process. Even assuming, *arguendo*, these statements were opinions, they are actionable because they did not "fairly align[] with the information in [Defendants'] possession at the time," *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 188-89 (2015).

IV. THE PSLRA SAFE HARBOR DOES NOT SHIELD DEFENDANTS' ALLEGED MISSTATEMENTS FROM LIABILITY.

The PSLRA provides Defendants no safe harbor here. The alleged false statements are not forward-looking because they relate to then-existing facts and conditions. Forward-looking statements are "statements whose truth cannot be ascertained until sometime after the time they are made[.]" DB 14 (quoting *In re Aegon N.V. Sec. Litig.*, 2004 WL 1415973, at *12 (S.D.N.Y. June 23, 2004)). But the truth of the misstatements here was known when uttered: Defendants knew when they were negotiating the "all-for-one" CVR milestone provision in the merger agreement and going forward that the expected value of the CVRs issued was ***$0***, because Defendants were going to delay the FDA approval process to render the CVRs worthless.[25]

[25] None of the cases Defendants cite aids their argument because in each the statements at issue were alleged to be misleading because they were "overly optimistic." *See, e.g.*, *Delcath*, 36 F. Supp. 3d at 334; *see also Sanofi*, 87 F. Supp. 3d at 524 (alleging defendants "failed to disclose flaws in the clinical trials that *decreased the likelihood* of obtaining timely FDA approval"); *Fort Worth Emps.' Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 221 (S.D.N.Y. 2009) (alleging defendants failed to disclose factor that "increased the risk" that FDA would not approve new drug). Those cases—involving an overestimate of the likelihood of success, but where plaintiffs still acknowledged success was ***possible***—are different in kind from the misconduct alleged here, where Defendants ***knew*** the likelihood of success was ***0%***, but went on suggesting otherwise.

Moreover, even assuming, *arguendo*, that certain statements at issue[26] were forward-looking, none of the three necessary safe harbor criteria are satisfied here. First, Defendants have waived any argument that the alleged misstatements are immaterial. *See* DB 14-18, 27-28. Second, the misstatements were not accompanied by meaningful cautionary language. Accompanying language is not meaningfully cautionary "if a reasonable investor could have been misled into thinking that the risk that materialized and resulted in his loss did not actually exist." *In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 333 (S.D.N.Y. 2014). Defendants offer a long list of instances of purportedly meaningful cautionary language, but none of these indicate Defendants planned to deliberately delay the FDA application process, nor do they convey that the then-actual value of the CVRs was $0. Rather, in each example of supposedly cautionary language, Defendants actually ***further misled*** investors into thinking the CVRs remained valuable. *See, e.g.*, DB 17 (the CVRs "ultimately ***may*** have no value"; "***If*** the CVR milestone . . . is not achieved for any reason . . . ."). Moreover, these statements are boilerplate warnings of general risk factors, rather than the "specific cautionary statements" required by the Safe Harbor provision. *See Delcath*, 36 F. Supp. 3d at 334; *MannKind*, 835 F. Supp. 2d at 817; *see also BioMarin*, 2022 WL 164299, at *8 (statement that "COVID-19 could postpone necessary interactions with regulators" and "delay review or approval" was insufficiently cautionary because it was not tailored to alleged misrepresentations regarding likelihood of approval by target date).

Third, Defendants had actual knowledge at the time of the alleged misstatements. *See BioMarin*, 2022 WL 164299, at *8 ("What happened between the FDA and BioMarin is, of course, within BioMarin's knowledge," and "it is plausible the defendants knew the truth was allegedly

[26] Defendants only challenge as forward-looking the statements they label Statements 1, 2, 3, 4, 6, 9, 10, 12, 13, 14, 15, 16, 18, 20, 23, 24. *See* DB 14, 27 & App'x 1.

otherwise."); *Reid*, 2010 WL 11710594, at *4 (Safe Harbor inapplicable because defendants "knowingly omitted important facts regarding FDA's serious concerns" about drug application and thereby "intentionally misled investors about the FDA's decision timetable by omitting the actual reasons for the delay"). As Plaintiffs allege, ***at the time of each alleged misstatement***, Defendants had a definitive plan to delay, but not prevent, FDA approval of Liso-cel, to avoid payout of the CVRs. ¶ 7. These allegations are based, in part, on evidence that Defendants repeatedly engaged in behavior so aberrational from industry norms that it could only be explained by such a plan, beginning with their insistence on the "all-for-one" CVR provision and ending with the bizarre series of errors that delayed FDA approval of the Milestone drugs. *See* ¶¶ 4, 5, 20, 22-23, 30, 96, 99-101, 108-116, 120-26, 214.

V. THE COMPLAINT ADEQUATELY PLEADS LOSS CAUSATION.

Two conditions must be satisfied for there to be loss causation: (1) "the loss be foreseeable"; and (2) "the loss be caused by the materialization of the concealed risk." *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173 (2d Cir. 2005). The former is satisfied if "the risk that caused the loss was within the zone of risk ***concealed*** by the [alleged] misrepresentations and omissions." *Id.* The latter is satisfied if "the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." *Id.* Plaintiffs have satisfied both inquiries. First, the risk that caused Plaintiffs' loss was Defendants' failure to obtain FDA approval of Liso-cel prior to the CVR deadline. This risk is squarely within the "zone of risk" concealed by Defendants—namely by their failure to disclose a plan to slow-roll FDA approval and their misstatements about acting with diligence. ¶ 16.[27]

[27] *See, e.g.*, *In re Bristol Myers Squibb Co. Sec. Litig.*, 586 F. Supp. 2d 148, 163-66 (S.D.N.Y. 2008) (loss causation adequately pled where announcement of criminal investigation "was not an isolated event in itself, [but] was instead the 'tip of the iceberg'—the first in a series of revelations

Second, these misstatements and omissions negatively affected the value of the CVRs. Most plainly, the disclosure of the fruits of Defendants' plan to slow-roll the FDA approval of Liso-cel resulted in a steady drumbeat of decline in the CVRs' value until it reached $0. ¶ 229. On May 6, 2020, the CVR price declined by 15% from the prior day, from $4.43 to $3.75 per share, in response to the press release in which Bristol announced that the FDA's target approval date for Liso-cel had been pushed back from August 17 to November 16, 2020. ¶ 225. The CVR price fell another 15% on September 8, 2020, following Bristol's disclosure that the Lonza facility would require an inspection and that neither of the two required plant inspections had occurred yet. ¶ 226. The CVR price plummeted 64% on November 5, 2020, due to statements in Bristol's Form 10-Q revealing only one facility had been inspected and the other facility's inspection had not even been scheduled. ¶ 227. The CVR price fell 43% on November 16, 2020, upon Bristol's announcement that Lonza facility inspection had been further delayed. ¶ 228.

Defendants argue Plaintiffs' loss causation theory is "speculat[ive]," DB 22, first by baldly mischaracterizing Plaintiffs' Complaint, *see, e.g.*, *id.* (falsely claiming Plaintiffs "acknowledg[e] that pandemic travel restrictions prevented the FDA from completing the facility inspections needed to approve the Liso-cel application" by citing to a portion of the Complaint which states, on the contrary, that "COVID-19-related inspection delays were not the reason Liso-cel missed the Milestone"). Defendants also mischaracterize the applicable case law, swapping out this Court's language about the speculative nature of assuming a company could "achieve[] all the results that management . . . projected that it could achieve" for a much broader claim that ***any***

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which would ultimately expose the Company's entire fraudulent scheme"); *In re Initial Pub. Offering Sec. Litig.*, 544 F. Supp. 2d 277, 299 (S.D.N.Y. 2008) (loss causation adequately pled because misrepresentations "concealed the alleged market manipulation that caused plaintiffs' losses[,]" and without them "plaintiffs' losses would not have occurred[, and] plaintiffs' losses are those that could be expected to result from the concealment of the market manipulation scheme).

assumptions regarding "different disclosures in [a] proxy statement" are speculative. *Compare* DB 22, *with Gray v. Wesco Aircraft Holdings, Inc.*, 454 F. Supp. 3d 366, 404 (S.D.N.Y. 2020). Drawing a causal relation between Defendants' misstatements regarding their plan to slow-roll FDA approval and the actual missed FDA approval deadline is ***not*** speculative.[28]

Finally, in arguing loss causation is speculative here, Defendants ignore entirely Plaintiffs' detailed pleading that other similar drugs were approved during the pandemic dramatically faster than Liso-cel. ¶¶ 32, 137-42. Again, the BLA for Gilead's competing drug Tecartus was submitted just 8 days before Liso-cel's BLA and was approved in July of 2020, at the height of the pandemic, and ***189 days faster*** than Liso-cel. ¶ 137. Moreover, for the 155 BLAs and other new drug applications the FDA reviewed under its Priority Review designation from 2014 to 2018, the FDA made a decision by its goal date ***98%*** of the time, and ***100%*** of the time from 2016 to 2018. ¶ 97.

VI. THE COMPLAINT PLAINLY PLEADS CONTROLLING PERSON CLAIMS.

Defendants concede the Individual Defendants were "controlling persons" under Securities Act § 15 and Exchange Act § 20(a). DB 35. Because Plaintiffs have pled primary violations of both the Securities Act and Exchange Act and that the Individual Defendants culpably participated in those violations, ¶¶ 256–61, Plaintiffs adequately stated controlling person claims, *see, e.g.*, *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 108 (2d Cir. 2007).

CONCLUSION

For the foregoing reasons, Defendants' motion should be denied.

[28] Defendants also argue that "[w]hile the price of CVRs allegedly declined after disclosures on May 6, September 8, November 5, and November 16, 2020, there are no facts alleged that would permit an inference that the price declines were in response to the revelation of fraud." DB 34 (internal citations omitted). This theory of loss causation is absurd: the market value of the Liso-cel CVRs was $0 when Defendants' scheme came to light because the milestone date elapsed. Under Defendants' theory, so long as an organization can conceal its illegal scheme until a CVR's deadline has passed, it cannot be held responsible for the billions it has cost investors.

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Respectfully Submitted,

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